APR 2 4 2003

3.0 SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by	Synovis Surgical Innovations 2575 University Ave. W. St. Paul, MN 55114 Tel: 651-603-3700 Fax: 651-603-5211
Contact Person	Angela Mallery At address above
Device Trade Name:	Veritas® Collagen Matrix
Common Name	Surgical Mesh
Classification Name	Mesh, Surgical 878.3300
Predicate device	Veritas® Collagen Matrix K002233 Synovis Surgical Innovations
Device Description	An implantable surgical patch comprised of non-crosslinked bovine pericardium. Veritas® Collagen Matrix undergoes proprietary processing that allows neo-collagen formation and neo-vascularization of the implanted device and permits replacement of the device with host tissue, or remodeling.
Statement of Intended use	Veritas® Collagen Matrix is intended for use as an implant for the surgical repair of soft tissue deficiencies, this includes but is not limited to the following: Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy / pneumectomy, pneumoreduction) and other incisions and excision of the lung and bronchus. Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. Abdominal and thoracic wall repair, muscle flap reinforcement, rectal and vaginal prolapse repair, urinary incontinence treatment, reconstruction of the pelvic floor, and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical).

Technological Comparisons	Veritas® Collagen Matrix is substantially equivalent to the predicate device, having the same technological characteristics and indication for use.
Testing	The Veritas® Collagen Matrix is substantially equivalent to the predicate device in term of testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2003

Ms. Angela Mallery
Regulatory Affairs Manager
Synovis Surgical Innovations
2575 University Avenue W.
St. Paul, Minnesota 55114

Re: K030879
Trade/Device Name: Veritas® Collagen Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: March 18, 2003
Received: March 20, 2003

Dear Ms. Mallery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030879

Device Name: Veritas® Collagen Matrix

Indications for Use:

Veritas® Collagen Matrix is intended for use as an implant for the surgical repair of soft tissue deficiencies, this includes but is not limited to the following:

Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy / pneumectomy, pneumoreduction) and other incisions and excision of the lung and bronchus.

Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.

Abdominal and thoracic wall repair, muscle flap reinforcement, rectal and vaginal prolapse repair, urinary incontinence treatment, reconstruction of the pelvic floor, and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030879

Prescription Use ✓ OR Over-The-Counter Use ____
Per 21 CFR 801.109